

ANTISEPTIC HAND SANITIZER FOAM- ethyl alcohol aerosol, foam
Higley Industries, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Antiseptic Hand Sanitizer Foam

Drug Facts

Active ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)
- do not reuse container. Dispose of properly

Inactive ingredients

Water, Glycerol, PEG-10 Dimethicone

Questions?

+1-800-535-5053

You may also report serious side effects to this phone number. ☐ Mon-Fri 9:00 AM - 5:00 PM

Since **H** 1923

Antiseptic

HAND SANITIZER

Foam

H Higley

Manufactured by: Higley Industries, Inc. 585 Huff St., Dubuque IA, 52003

WWW.HIGLEYINC.COM

Packaging



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DRUG FACTS LABEL

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ANTISEPTIC HAND SANITIZER FOAM

ethyl alcohol aerosol, foam

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65584-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65584-105-12	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/19/2020	

Labeler - Higley Industries, Inc. (005467626)

Establishment

Name	Address	ID/FEI	Business Operations
Higley Industries, Inc.		005467626	manufacture(65584-105)

Revised: 3/2020

Higley Industries, Inc.